REMARKS

Objection to Specification and Claim 17

The Examiner has asked that Applicants correct the usage of certain trademarks in the specification, and replace these trademarks with the generic terminology in claim 17. This has been done by amendment.

Status of Claims

Claims 1-59 are in the case. Claims 1, 17, 34 and 43-46 have been amended. Claims 47-59 have been added by amendment. Claims 2-16, 18-33, 35-39 and 41-42 remain unchanged. No new matter has been added. Support for the new claims is found in Applicants' specification, for example at the locations listed in the following table:

New claim	Support
47	p. 9, lines 3-4
48	p. 9, lines 10-26
49	p. 2, line 31 and p. 3, line 1
50 and 51	p. 10, lines 8-9
52	p. 11, lines 5-7
53 and 54	p. 5, lines 16-17 and p. 6, lines 9-11
55	p. 6, lines 20-21
56 and 57	p. 6, lines 17-18, p. 8, lines 19-22, p. 10, lines 27-28
58	p. 6, line 31 and p. 7, line 1
59	original claims 40 and 44

Applicants gratefully acknowledge the Examiner's indication that claims 1-39 are allowable over the art of record. While claim 1 has been amended, and further art is submitted herewith, Applicants respectfully submit that claims 1-39 remain in condition for allowance.

The Examiner has also indicated that claim 44 is objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form. Claim 44 depends from claim 1, which is not rejected. Thus, Applicants believe that the Examiner means to indicate that independent claim 40 -- which is rejected -- would be allowable if it included the language of claim 44. Based on this assumption, Applicants have added new claim 59, which combines the features of claims 40 and 44.

Rejection Under 35 U.S.C. §103(a)

Claims 40-43 and 45-46 have been rejected as being unpatentable over Butler et al. in view of Stensaas et al.

Neither of the cited references discloses or suggests a method that includes rolling a support around a nerve. Instead, Butler discloses a pre-formed, cylindrical cell encapsulating device that is implanted into an individual to supply therapeutic substances to the individual. Stensaas discloses a pre-formed (e.g., molded) cylindrical prosthesis into which the ends of a severed nerve can be inserted.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

Applicants also note that claims 43-46 depend from claim 1 and thus should be allowable therewith.

Conclusion

Attached is a marked-up version of the changes being made by the current amendment.

Applicants ask that all claims be allowed. Enclosed is a $183 check for excess claim fees and a $205 check for the Petition for Two Month Extension of Time fee. Please apply any other charges to Deposit Account No. 06-1050, referencing Attorney Docket No. 00786-446001.

Respectfully submitted,

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Version with markings to show changes made

In the specification:

Paragraph beginning at page 10, line 12 has been amended as follows:

--Some embodiments of the invention include a polymer hydrogel layer 22 adhered to the support 12 or to a layer of cells 26 adhered to the support 12. The polymer hydrogel layer 22 can be any biocompatible, bioresorbable polymer gel that provides an aqueous milieu for cell migration and neurotrophic agent diffusion. The hydrogel can be natural or synthetic. The hydrogel layer 22 can have a thickness from 5 to 120 μm, preferably from 10 to 50 μm, e.g., approximately 20, 25 or 30 μm. Optimal hydrogel thickness depends on factors such as the diameter of the nerve being repaired and the number and diameter of microspheres 24 (if any) to be accommodated in the hydrogel layer 22. Exemplary materials for use in a polymer hydrogel layer 22 are fibrin glues, [Pluronics]PLURONICS® hydrogels, polyethylene glycol (PEG) hydrogels, agarose gels, PolyHEMA (poly 2-hydroxyethylmethacrylate) hydrogels, PHPMA (poly N-(2-hydroxypropyl) methacrylamide) hydrogels, collagen gels, [Matrigel]MATRIGEL® hydrogels, chitosan gels, gel mixtures (e.g., of collagen, laminin, fibronectin), alginate gels, and collagen-glycosaminoglycan gels. The hydrogel layer 22 can contain one or more neurotrophic agents or axon extension-promoting proteins. Such neurotrophic agents can be loaded directly into the hydrogel 22, loaded into microspheres 24, or incorporated into the support or spacers as described herein.--

In the claims:

Claims 1, 17, 34, 40 and 43-46 have been amended as follows:

--1. (Amended) A nerve regeneration conduit comprising a porous biocompatible support comprising an inner surface and an outer surface, the support being in the form of a roll such that a cross section of the roll approximates a spiral [spanning from 8 to 40 rotations], with the outer surface of the support facing outward, relative to the origin of the spiral.

17. (Amended) The nerve regeneration conduit of claim 14, wherein the hydrogel layer comprises a polymer selected from the group consisting of fibrin glues, [Pluronics®] block ABA copolymers of poly(oxyethylene) and poly(oxypropylene), polyethylene glycol (PEG) hydrogels, agarose gels, PolyHEMA (poly 2-hydroxyethylmethacrylate) hydrogels, PHPMA (poly N-(2-hydroxypropyl) methacrylamide) hydrogels, collagen gels, [Matrigel®] soluble basement membrane extracts, chitosan gels, gel mixtures [(e.g., of] comprising two or more of collagen, laminin, and fibronectin[])], alginate gels, and collagen-glycosaminoglycan gels.

34. (Amended) A method of manufacturing a nerve regeneration conduit, the method comprising providing a porous biocompatible support comprising an inner surface and an outer surface; and forming the support into a roll such that a cross section of the roll approximates a spiral [spanning from 8 to 40 rotations], with the outer surface of the support facing outward, relative to the origin of the spiral.

43. (Amended) The nerve [regenerating] regeneration conduit of claim 14, wherein the hydrogel further comprises cells.

44. (Amended) The nerve [regenerating] regeneration conduit of claim 1, wherein the support further comprises spacer members extending from the inner surface of the support.

45. (Amended) The nerve [regenerating] regeneration conduit of claim 1, wherein the support is loaded with one or more neurotrophins.

46. (Amended) The nerve [regenerating] regeneration conduit of claim 45, wherein the one or more neurotrophins are distributed in a gradient in the support.--